

Number: GZHT02280165-S1

THIS IS TO SUPERSEDE REPORT NO. GZHT02280165 DATED Apr 23, 2020

Report Ref:	GZHT02280165-S1		
Date Received:	Apr 13, 2020	Date Issued:	May 09, 2020

Company Name: Address:	
Contact Name:	

The Following Sample Was Subm	itted And Identified By/On Behalf Of The Applicant As:
End Uses :	Non-Sterile Medical Face Mask
Ratings :	Type II/Type IIR
Sample Name :	Disposable Medical Face Mask
Size :	17.5cmx9.5cm
Colour	Blue
Standard :	EN 14683:2019+AC:2019
Brand	
Manufacturer	
Date received/ Test Started :	Apr 13, 2020
Ref :	Type: DQSM01
	Product Registration Number: 鄂械注准 20162642299

Prepared And Checked By:

For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin General Manager

Can / pennytao



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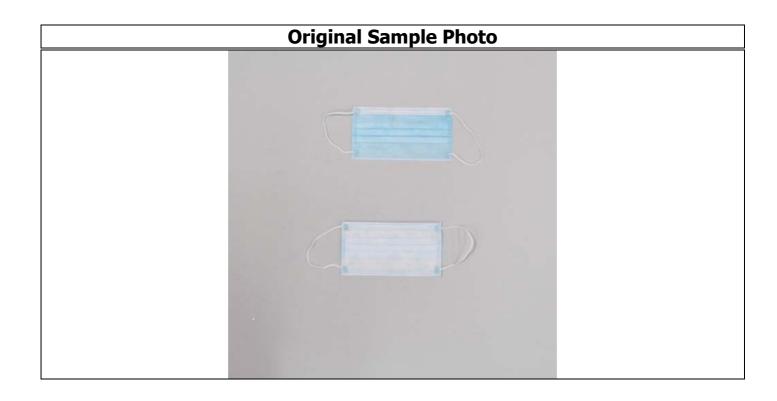
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Summary of testing:

With reference to following standard:

EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type II & Type IIR

Materials Used in The Submitted Sample Were Found To Comply With The Type II Requirements of EN 14683:2019+AC:2019 with respect to Microbial Cleanliness, Differential Pressure and Bacterial Filtration Efficiency tests.

Materials Used in The Submitted Sample Were Found To Comply With The Type IIR Requirements of EN 14683:2019+AC:2019 with respect to Microbial Cleanliness, Differential Pressure, Bacterial Filtration Efficiency and Splash Resistance Pressure tests.

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Tests Conducted (As Requested By The Applicant)

Bacterial Filtration Efficiency (EN 14683:2019+AC:2019, Clause 5.2.2, Testing Refer To Annex B): Flow rate: 28.3L/min, Test area: 77 cm², Test bacteria: Staphylococcus aureus ATCC 6538, Inside of the test mask was facing towards the challenge aerosol, The average plate count results of the positive controls: 2.4x10³ CFU, The average plate count results of the negative controls: <1 CFU.

<u>Tested Sample</u>	Result (%)	Performance Requirement for Medical Face Mask Type II: ≥ 98% Type IIR: ≥ 98%
Specimen (1) Specimen (2) Specimen (3) Specimen (4)	99.6 99.5 99.3 99.5	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Specimen (5)	99.5	

Remark: Test was conducted by external provider

2 Differential Pressure (EN 14683:2019+AC:2019 Annex C):

Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm².

<u>Tested Sample</u>	<u>Result (Pa/cm²)</u>	<u>Performance</u>
		Requirement for
		Medical Face Mask
		Type II: < 40 Pa/cm ²
		Type IIR: < 60 Pa/cm ²
Specimen (1)	34.0	
Specimen (2)	36.4	
Specimen (3)	39.8	
Specimen (4)	38.7	
Specimen (5)	39.3	
Average	37.6	

Remark: Test was conducted by external provider

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Tests Conducted (As Requested By The Applicant)

3 Splash Resistance Pressure (ISO 22609:2004):

Synthetic Blood Surface Tension: 0.041N/m, Distance Between Blow Head Front End And Target Area: 300 mm, Artificial Blood Volumes: 2 mL, Test Pressure: 16.0 kPa, Velocity: 550 cm/s, Use A Fixed Target.

<u>Tested Sample</u>	<u>Result</u>	Performance Requirement for Medical Face Mask Tpye IIR: No penetration at 16.0 kPa
Specimen (1)	None Seen	
Specimen (2)	None Seen	
Specimen (3)	None Seen	
Specimen (4)	None Seen	
Specimen (5)	None Seen	
Specimen (6)	None Seen	
Specimen (7)	None Seen	
Specimen (8)	None Seen	
Specimen (9)	None Seen	
Specimen (10)	None Seen	
Specimen (11)	None Seen	
Specimen (12)	None Seen	
Specimen (13)	None Seen	

Remark: Test was conducted by external provider

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Tests Conducted (As Requested By The Applicant)

4 Microbial Cleanliness

As per BS EN 14683:2019 Medical face masks-Requirements and test methods Annex D.

Test Item	Result (cfu/g) (1)				<u>Limit</u>	
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	<u>(cfu/g)</u>
Microbial cleanliness	<1#	<1#	<1#	2	<1#	Type II: ≤30 Type IIR: ≤30

Remark:

cfu = Colony Forming Unit

 \leq = Not More Than

= No Colony Was Detected At The Extraction Liquid Of The Samples.

Tested Component:

(1) Blue Face Mask

End of Report

This report is made solely on the basis of your instructions and/or information and materials supplied by you. It is not intended to be a recommendation for any particular course of action. Intertek does not accept a duty of care or any other responsibility to any person other than the Client in respect of this report and only accepts liability to the Client insofar as is expressly contained in the terms and conditions governing Intertek's provision of services to you. Intertek makes no warranties or representations either express or implied with respect to this report save as provided for in those terms and conditions. We have aimed to conduct the Review on a diligent and careful basis and we do not accept any liability to you for any loss arising out of or in connection with this report, in contract, tort, by statute or otherwise, except in the event of our gross negligence or wilful misconduct. No copy of the test report(except for full text copy) shall be made without the written approval by Intertek.

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